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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,206	08/05/2003	Russell Powers	4002-3357/PC934.00	6826

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KRIEG DEVAULT LLP
ONE INDIANA SQUARE, SUITE 2800
INDIANAPOLIS, IN 46204-2709

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/634,206

Applicant(s)

POWERS ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,5-20,22-28,30,31,33-39 and 56-72 is/are pending in the application.
- 4a) Of the above claim(s) 10-16,18,19,27,28,30,31,33-39 and 56-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,5-9,17,20 and 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/4/07 has been entered.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the limitation that the packaging comprises a "common container" was not found in the written description.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3,5-9,17,20,22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what is meant by "common container". Does it mean that the components are together such that they are mixed or just that it is the same container with possible individual compartments formed of an inner package?

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3,17,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henniges et al. (2002/4660) in view of Murphy (6273916). Henniges et al. shows (Fig. 1) a surgical plate **10** and a number of bone screws **12** to secure the plate. Fig. 11A shows a driver instrument **24** with a shaft or first portion **372** and a second handle portion **15** and an end portion to drive the screws into bone. The driver is fully capable of performing "multiple functions". Henniges et al. disclose the equipment is packaged, paragraph 60. However, Henniges fails to disclose the spinal plate, screws and instrumentation in a *common container* and in sterile condition. Murphy teaches a surgical kit for spinal surgery including all the components in a common container and sterile condition, col. 3, lines 6-10, col. 4, lines 31-37. Murphy shows (Fig. 4) the spinal surgery kit includes all components, including instrumentation. It would have been obvious to one of ordinary skill in the art to use a "common container" for the spinal surgery kit as taught by Murphy with the spinal plate, screws and instrumentation of Henniges et al. so that it reduces the packaging used and costs involved in manufacturing the kit and provides all the components required for easy retrieval by the surgeon.

Claims 5,6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henniges et al. (2002/4660) in view of Murphy '916 as applied to claim 3 above, and further in view of Ray (2001/20185). Henniges et al. in view of Murphy is explained

supra. However, Henniges et al. as modified by Murphy fail to disclose an interbody implant with the spinal plate device. Ray teaches interbody implants are placed between first and second vertebrae, paragraph 20. Ray shows (Fig. 2) a plate member and an interbody implant (Fig. 3) that are part of a "kit" used together as shown in Fig. 1. It would have been obvious to one of ordinary skill in the art to include an interbody implant for fusing vertebrae with a plate member as taught by Ray into the kit of Henniges et al. in view of Murphy such that it enables the surgeon to correct for weakened vertebrae and provides more stabilization.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henniges et al. (2002/4660) in view of Murphy '916 as applied to claim 3 above, and further in view of Wagner et al. (5306309). Henniges et al. in view of Murphy is explained supra. However, Henniges et al. as modified by Murphy fail to disclose instruments designed for disposal or single use. Wagner teaches that an instrument for spinal surgery is used and designed for planned disposal, col. 4, lines 9,10. It would have been obvious to one of ordinary skill in the art to utilize a discardable instrument as taught by Wagner et al. for the driver of Henniges et al. as modified by Murphy such that no germs, bacteria etc. can be spread to another patient by providing an instrument to discard or one time use.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henniges et al. (2002/4660) in view of Murphy '916 as applied to claim 3 above, and further in view of Paikoff et al. (4523679). Henniges et al. in view of Murphy is explained supra. However, Henniges et al. as modified by Murphy fail to specifically

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disclose a plurality of compartments to hold the kit components or that there is an inner and outer container to maintain sterility or that the packaging is clear. Paikoff et al. show packaging for medical instrumentation with a plurality of compartments. Paikoff also teaches that the packaging is formed with an inner and outer container, col. 3, lines 55-65, col. 4, lines 38-43. It is also well known that the plastic is clear such that the surgeon can see what is in the package. Paikoff additionally teaches that the different compartments are used to allow for different sterilized products, col. 3, lines 42-45, 65-68. It would have been obvious to one of ordinary skill in the art to use multi compartments as taught by Paikoff to package the spinal kit of Henniges et al. as modified by Murphy so that no damage is done to the different components of the kit while packaged and sterilized under sterilization procedures.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henniges et al. (2002/4660) in view of Murphy '916 as applied to claim 3 above, and further in view of Banick et al. (2003/93153). Henniges et al. in view of Murphy is explained supra. However, Henniges et al. as modified by Murphy fail to disclose a template with images. Banick et al. show (Fig. 7) a surgical kit **60** for use in spinal surgery comprising spinal components and a template. It is well known that templates or instructions include images of apparatus of use for surgeries. It would have been obvious to one of ordinary skill in the art to include a template with images as taught by Banick et al. in the kit of Henniges et al. as modified by Murphy such that it enables a surgeon or doctor to be provided with dimensions of the device for consideration after

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possibly making measurements or evaluation of the patient's anatomical implantation site.

Response to Arguments

Applicant's arguments with respect to claim 3 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Fr (8:30am-5pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

**BRIAN E. PELLEGRINO
PRIMARY EXAMINER**

Brian E Pellegrino